K131058

510(k) Summary
for Boston Endo Surgical Technologies (division of Lacey Manufacturing)
Bipolar Forceps

1. SUBMITTER/510(K) HOLDER

Boston Endo Surgical Technologies (division of Lacey Manufacturing)
1146 Barnum Avenue
Bridgeport, CT 06610

Contact Name: James Rogers
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Telephone: (203) 336-7453

Date Revised: July 1, 2013

Prepared By: JA

2. DEVICE NAME

Proprietary Name: Bipolar Forceps
Common/Usual Name: Bipolar Forceps
Classification: Class 2, 21 CFR 878.4400
Classification Name: Electrosurgical Cutting and Coagulation Accessories
Product Code: GEI

3. PREDICATE DEVICES

- K032327 Modern Medical Bipolar Forceps

4. DEVICE DESCRIPTION

The Bipolar Forceps device is a single use hand held insulated medical device approximately 295mm in overall length featuring a 190mm distance from the user's grasp to the tip. The bayonet offset is 1.5cm. The tips are Titanium Nitride coated and have polished contact surfaces 1.5mm wide by 1cm long. The device is offered in straight and 20 degree angled tips. The Bipolar Forceps are sold as a single use sterile packaged device used in general surgical procedures.

The Bipolar Forceps are limited to maximum 70 watts and shall be used only by personnel with training in electrosurgical procedures and with compatible generators compliant with IEC 60601 requirements. The Bipolar Forceps are rated at 1000V peak and can be used with a compatible reusable pin plug cable (1.8mm

pin, 5.8mm spacing). The Bipolar Forceps are single use disposable devices packaged in double blisters with Tyvek lid.

5. INTENDED USE

Tissue grasping and control of bleeding of small vessels by bipolar coagulation.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Bipolar Forceps substantially equivalent to the Modern Medical Bipolar Forceps cleared under 510(k) K032327. The only difference between the devices is that the subject device is provided sterile and is for one time use, whereas the predicate device is reusable. The materials and design are identical.

7. PERFORMANCE TESTING

Biocompatibility testing for the intended application of the Bipolar Forceps was performed as suggested by the International Standards Organization (ISO) 10993 Guidelines, FDA General Program Memorandum No. G95-1 and the Office of Device Evaluation (ODE) Bluebook Memorandum G95-1 "Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

Test	Conclusion
Cytotoxicity	Non-cytotoxic
Irritation	Non-irritating
Sensitization	Non-sensitizing

The device was also subjected to performance testing after sterilization using animal tissue of various diameters to simulate vessels at different power settings. The device properly cut and coagulated the tissue.

8. SAFETY AND EFFICACY

The subject device was subjected to testing including:

- Electrical safety
- Biocompatibility
- Packaging validation
- Shipping & transportation
- Aging Shelf Life
- Hi-Pot

The testing found no issues of safety or effectiveness.

9. CONCLUSION

Boston Endo Surgical Technologies believes that based on the indications for use, technological characteristics, and comparison to predicate devices the Bipolar Forceps has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Boston Endo Surgical Technologies, Incorporated
Mr. James Rogers
Regulatory Affairs, Manager
1146 Barnum Avenue
Bridgeport, Connecticut 06610

October 25, 2013

Re: K131058
Trade/Device Name: Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 14, 2013
Received: August 16, 2013

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131058

Device Name: Bipolar Forceps

Indications for Use:

Tissue grasping and control of bleeding of small vessels by bipolar coagulation.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.11.05 06:44:29 -05'00'

for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K131058